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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,275	03/17/2000	Klaus Unsicker	2896.1002001	3131

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/01/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/527,275

Applicant(s)

UNSICKER ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 and 60-62 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,6-15 and 17-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 16, 57-58, 60-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 19, 2003 has been entered.

Response to Amendment

2. Claims 1, 57 and 58 have been amended, claims 60-62 have been added and claim 59 has been cancelled, as requested in the amendment of Paper No. 25, filed on May 19, 2003, and further clarified in the supplemental amendment of Paper No. 26. Claims 1-58 and 60-62 are pending in the instant application.

Claims 3-4 and 6-15 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 17-56 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to invention nonelected by original presentation, see section 3 of Paper No. 9.

Claims 1, 2, 5, 16, 57-58 and 60-62 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on May 19, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment of claim 1 has introduced a new matter into the claim by presenting additional new limitations regarding specific combinations of the recited cytokines, which are not supported by the instant specification, as originally filed. Applicant submits that support for this amendment can be found at page 2, line 25 through page 3, line 15 and throughout the specification (see page 3, section Claim Amendments of the Response). However, the Examiner fails to find support for such recitations within the specification at the noted passages. On the contrary, the instant specification, as filed discloses only a composition comprising at least two cytokines, wherein at least one cytokine is BMP, GDF, TGF- β or GDNF (see page 2 last paragraph and page 3, first paragraph of the instant specification, and also the original claim 1).

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The instant specification fails to provide adequate support or written description for any inclusion, exclusion or a specific combination of cytokines within the claimed composition, thus introducing a new inventive concept into the claims. Any negative limitation or exclusionary proviso must have basis in the original disclosure. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph. See MPEP 2173.05 (i).

Claim Rejections - 35 USC § 102

7. Claims 1, 2, 5, 16 and 57-58 stand rejected under 35 U.S.C. 102(b) as being anticipated by Goulin et al. (J. Neurosci. Res., February 15, 1996) for reasons of record in section 6 of Paper No. 14 and also in section 5 of paper No. 18.

Briefly, Goulin et al. teach a composition of at least two cytokines, which are, a first cytokine, GDNF and a second cytokine, TGF- β 3, such composition having neurotrophic activity (see page 461, second column, first paragraph), which meets the material limitations of claims 1, 2, 5, 57 and 59. Because the composition of Goulin et al. comprises the same ingredients as the claimed instant composition, it inherently has the same properties, such as synergistic activity, see MPEP 2112. Thus, the composition of the instant claims 1, 2, 5, 57 and 59 was fully disclosed by Goulin et al.

Applicant argues that claims 57-58, as amended recite "consisting two cytokines, wherein the two cytokines are GDNF and TGF- β " (see bottom at page 2 of the Response of Paper No.

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26). However, claims 57-58, as currently amended, recite "comprising two cytokines". MPEP 2111.03 states that "The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Therefore, using open language in the claim, such as "comprising", does not exclude the presence of other ingredients, including other cytokines.

Furthermore, the composition of GDNF and TGF- β 3 was used in serum-free culture medium (see section Materials and methods), which clearly can be considered as a "pharmaceutically acceptable diluent". Applicant argues that "one of ordinary skill in the art would not consider complete basal medium containing, inter alia, insulin, sodium selenite, progesterone, putrescine, penicillin and streptomycin (page 455, column 1-2) a pharmaceutically acceptable carrier or diluent" (middle at page 4 of the Response of Paper No. 25). This has not been found to be persuasive because the composition of GDNF and TGF- β of Goulin et al. clearly comprised L-15, a serum-free media, which obviously is considered as a pharmacologically acceptable diluent. There is nothing in the claim 16 that excludes other ingredients to be present in the composition comprising GDNF and TGF- β and further comprising a pharmacologically acceptable diluent.

Thus, claims 1, 2, 5, 16 and 57-58 are anticipated by the disclosure of Goulin et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1, 2, 5, 16, 57-58 and 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is vague and indefinite for recitations "first cytokine" and "second cytokine". Because it appears that there is no order of addition or any dominance between the recited cytokines, the basis of using these recitations is not obvious. Applicant is advised to consider revising the claim language including recitation "wherein if TGF- β is present, then NT-3, NT-4 or FGF are not present", perhaps.

10. Claims 1, 57-58, 60-62 are vague and ambiguous for recitation "functionally active derivatives or parts thereof". It is not clear if "parts thereof" refer to the cytokines or to "functionally active derivatives". Further, according to the instant specification, "functionally active derivative" [...] refer[s] to a proteinous compound exhibiting at least part of the biological function of the respective cytokine" (page 3, lines 4-5). One skilled in the art readily understands that a cytokine usually displays plurality of biological activities. It is not clear what biological activity, or part of it, a "functionally active derivative" has to exhibit in order to meet the limitations of the claimed subject matter.

11. Claims 2, 5, 16 are indefinite for being dependent from the indefinite claim.

Allowable subject matter

12. Applicant is advised that a claim directed to "a composition consisting of GDNF and TGF- β ", or to "a composition consisting essentially of GDNF and TGF- β ", or to "a composition

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consisting of GDNF and TGF- β further comprising a pharmaceutically acceptable carrier" is free of prior art.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative

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number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
June 26, 2003

